



MEMORANDUM  
**EFFECTIVE IMMEDIATELY**  
June 10, 2009

To: St. Luke's Investigators and Research Staff

From: Ted Walters, MD and Norm Jensen, JD  
Co-Chairs, St. Luke's Institutional Review Board

Subject: Management of External Serious Adverse Event (SAE) and Safety Reports

The Office of Human Research Protections (OHRP) and the Food and Drug Administration (FDA) have issued recent guidance regarding the reporting requirements for adverse events and unanticipated problems involving risks to subjects or others. According to federal regulations, only when an adverse event rises to the level of an unanticipated problem involving risks to subjects or others (or an unanticipated adverse device effect) do the regulations require reporting to the IRB. Both OHRP and the FDA advise that it is neither useful nor necessary for reports of individual adverse events occurring in subjects enrolled in multi-center studies to be distributed routinely to investigators or IRBs at all institutions conducting the research. Adverse events occurring in a multi-center studies should be reviewed and analyzed by the sponsor, a Data and Safety Monitoring Board (DSMB) or a monitoring entity that assesses whether the adverse event occurrence is both unanticipated and a problem for the study.

In accordance with the above-referenced guidance:

- Investigators will NOT be required to submit nor will the IRB accept or review individual SAEs occurring at sites outside the jurisdiction of St. Luke's IRB unless in the local investigator's opinion the adverse event represents an unanticipated problem (the adverse event is unexpected, reasonably related to the study drug or study procedure(s) and suggests the research places subjects at greater risk of harm than was previously known.). If the sponsor requires reporting, these reports can be compiled at the time of continuing review on a tracking log and submitted to the IRB.

St. Luke's IRB will accept and review the following:

- Summary safety reports from the sponsor, i.e. Data and Safety Monitoring Board (DSMB) reports and/or quarterly, biannual or annual reports when provided. Such reports should provide an overview of the analysis of events, assessment of the risk/benefit ratio and any actions required as a result of the safety review. Line listings of safety events may be provided as part of the summary report.
- Reports of **local** adverse events occurring at sites for which St. Luke's serves as the IRB of record that meet the IRB reporting requirements.

It is anticipated that this new process will help to decrease the amount of unnecessary reporting to the IRB so that those safety reports which are of potential concern may be given the IRB time and focus that is needed.

This change in policy does not alter investigator reporting responsibilities specified in the research protocol, contract, other study documents or the federal regulations.

Investigators should refer sponsors to the new reporting requirements. Please direct any questions regarding the new reporting requirements to Julie Wall, IRB Manager, Office of Research Administration/IRB at 208-381-1406.

**Please Note:** This memorandum only pertains to the management of external serious adverse events (SAEs) and local adverse event reporting.